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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,740	09/29/2003	Wei Liu	01997.022600	8198

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EXAMINER

PHAM, AUDREY S

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,740

Applicant(s)

LIU ET AL.

Examiner

Audrey S. Pham

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on December 16, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 10-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Liu *et al.*

Claims 1-25 are pending

Claims 1-5, 10-25 have been withdrawn from further consideration by the examiner under 37 CFR 1. 142(b) as being drawn to non-elected inventions.

Claims 6-9 are under consideration.

Examiner's Response to Election/Restriction

The Election filed on December 16, 2005, in response to the Office Action Requirement for Restriction dated November 17, 2005 is acknowledged and has been entered. Applicant elected Group IV, Claims 6-9 without traverse and without waiving any right to prosecute the cancelled claims or similar claims in the future. Applicant requests for a rejoinder of the appropriate process claims upon the allowance of the elected product claims. Applicant is reminded that the right to a rejoinder applies only to those invention(s) in which all claims to non-elected process invention must depend from or otherwise require all the limitations of an allowable claim (MPEP 821.04). Applicant is advised that, in order to retain the right to rejoinder, the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention.

Claims 1-5, 10-25 are withdrawn by the examiner in response to the restriction requirement. Thus, Claims 6-9 are pending and are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected as vague and indefinite for reciting the term "Ki-24" as the sole means of identifying the claimed molecule. The use of a laboratory designation only to identify a particular molecule renders the claims indefinite because different laboratories may use the same designation to define completely distinct molecule. The specification only denotes Ki-24 as an anti-70 monoclonal antibody (page 1, paragraph 002, line 5). The rejection can be obviated by amending the claims to specifically and uniquely identify Ki-24 by a SEQ ID NO.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Law *et al.* (WO2004073656, filed February 2003).

Claim 6 is drawn to a pharmaceutical composition comprising a hybrid molecular structure itself comprising a molecule that specifically targets CD70 linked to a cellular killing agent and a pharmaceutically acceptable carrier, wherein the composition destroys malignant kidney tissue. Claim 7 is drawn to the pharmaceutical composition of claim 6 wherein the malignant kidney tissue is renal cell carcinoma tissue or clear cell renal cell carcinoma tissue. Claim 8 further limits claim 6 wherein the cellular killing agent is a calicheamicin or a

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calicheamicin derivative. Claim 9 further limits claim 6 wherein the molecule that specifically targets CD70 is CD27 or Ki-24.

Law *et al.* teach a pharmaceutical composition (page 57, paragraph 0197) comprising a hybrid molecular structure (page 25, paragraph 0107) linked (page 42, paragraph 0159) to a cellular killing agent (page 57, paragraph 0197+) and a pharmaceutically acceptable carrier (page 24, line 35) wherein the composition destroys malignant kidney tissue (page 8, paragraph 0027) such as renal cell carcinoma (page 8, line 32). Specifically, Law *et al.* teach a method of using the composition comprising an anti-CD70 antibody (page 8, paragraph 0024) conjugated to cytotoxic agents including calicheamicin (page 8, paragraph 0025) that specifically targets CD70-expressing cells (page 6, lines 23-25) for the treatment of CD70-expressing cancers (page 6, line 25). It is noted that the specification teaches (page 1, paragraph 002, line 5) that Ki-24 denotes an anti-CD70 monoclonal antibody. Thus, Claim 9 is anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Law *et al.* (WO2004073656, filed February 2003) and further in view of Damle *et al.* (Current Opinion in Pharmacology, Vol 3, pages 386-390, August 2003).

Law *et al.* teach Claims 6-9 as set forth above.

Law *et al.* do not specifically teach a cellular killing agent wherein the agent is a calicheamicin derivative (Claim 8).

Damle *et al.* teach a cytotoxic agent N-acetyl gamma calicheamicin, which is identified in the specification of the instant application as a calicheamicin derivative (page 39, paragraph 0103), conjugated to a monoclonal antibody specific for tumor-associated antigens for treating human cancer (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention, was made to link a calicheamicin derivative with a molecule that specifically target CD70, as taught by Law et al, for the purposes of treating kidney cancer. One would have been motivated to do so because it is conventional in the art to combine a cytotoxic agent with a monoclonal antibody for improved anti-tumor efficacy. It can be advantageous to use the anti-CD70 antibody conjugated with a calicheamicin derivative for treating cancer because the N-acetyl gamma calicheamicin improves the therapeutic index of its antibody conjugate (Damle, page 386, column 2 last paragraph), which is much needed in the art because of the difficulty of retaining a potency advantage (page 387, column 1 first paragraph 1). Further, one of ordinary skill in the art would have a reasonable expectation of success at treating cancer because the antibody-calicheamicin derivative conjugate has been shown to exhibit strong anti-tumor activity (page 387 column 1 paragraph 1) and has received regulatory approval (page 287 column 1 paragraph 2).

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Audrey S. Pham whose telephone number is (571) 272-3323. The examiner can normally be reached during the hours of 8:30 AM - 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached during business hours at the telephone number: (571) 272-0787. The fax number for the organization, where this application or proceeding is assigned, is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Audrey S. Pham
Patent Examiner
Art Unit 1642

A handwritten signature in black ink, reading "Gary B. Nickol". The signature is written in a cursive, flowing style.

**GARY B. NICKOL, PH.D.
PRIMARY EXAMINER**